



DG Health and Food Safety
Unit Information Systems (SANTE.A4)

Data Exchange for CAs – User Guide

EUDAMED: v2.8

July 2022

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1 MACHINE TO MACHINE DESCRIPTION

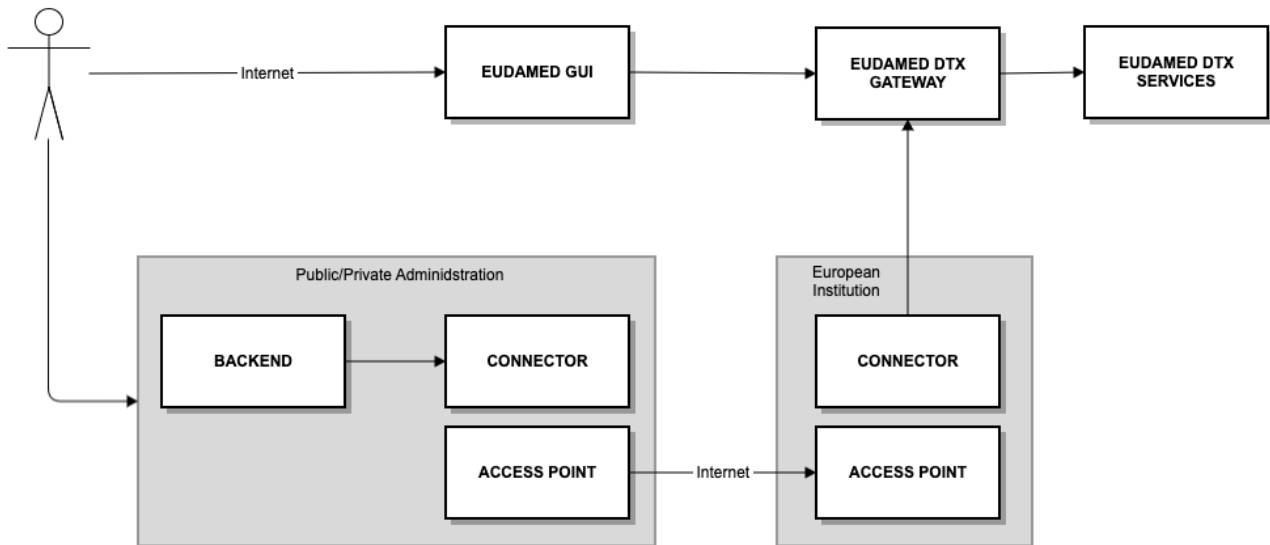


Figure 1: EUDAMED DTX; M2M and Bulk Upload/Download

For each use case, sample XML files will be circulated in order to help users test functionality. For the Playground environment, any reference to XSD files refer to that which has been circulated to Playground users. Please note that the playground XSD may differ to the XSD files available via the production EUDAMED or via the [Europa Medical Device website](#).

This document will explain the details of how to access the security token which is required for M2M connection with EUDAMED. It will NOT cover technical aspects of onboarding connections via eDelivery, which will occur *after* the steps in this document. Nonetheless, we encourage you to review the [CEF eDelivery access point documentation](#) as they may have been updated, and in particular their Access Point Test Guide available [here](#).

1.1 Contents of sent messages

Please note: the payload of messages is base64 encrypted, and a sent message for M2M will look something like that outlined in section 1.4.

Samples of XML files and responses for bulk upload and download are available alongside this document. You will notice that when compared with M2M, there is a key difference: The serviceAccessToken. This token is specific for each module of EUDAMED, and the combination of this token and the SRN of the sender is used as security to ensure that the message is received from the correct actor.

Important: Without this token, your message will not pass our security checks. An incorrect token will give the following error response:

```
<message:elementReport>
  <message:operationErrorCode>M-50000</message:operationErrorCode>
  <message:operationErrorDetail>The access point code is not valid: please contact the support</message:operationErrorDetail>
</message:elementReport>
</message:report>
<message:responseCode>SERVER_ERROR</message:responseCode>
</message:PullResponse>
```

1.2 How to generate your access token in EUDAMED

1. After you log into EUDAMED as a Local Actor Administrator, you will see the link “Machine to machine data delivery preferences” under the “My Actor data” section of your dashboard:

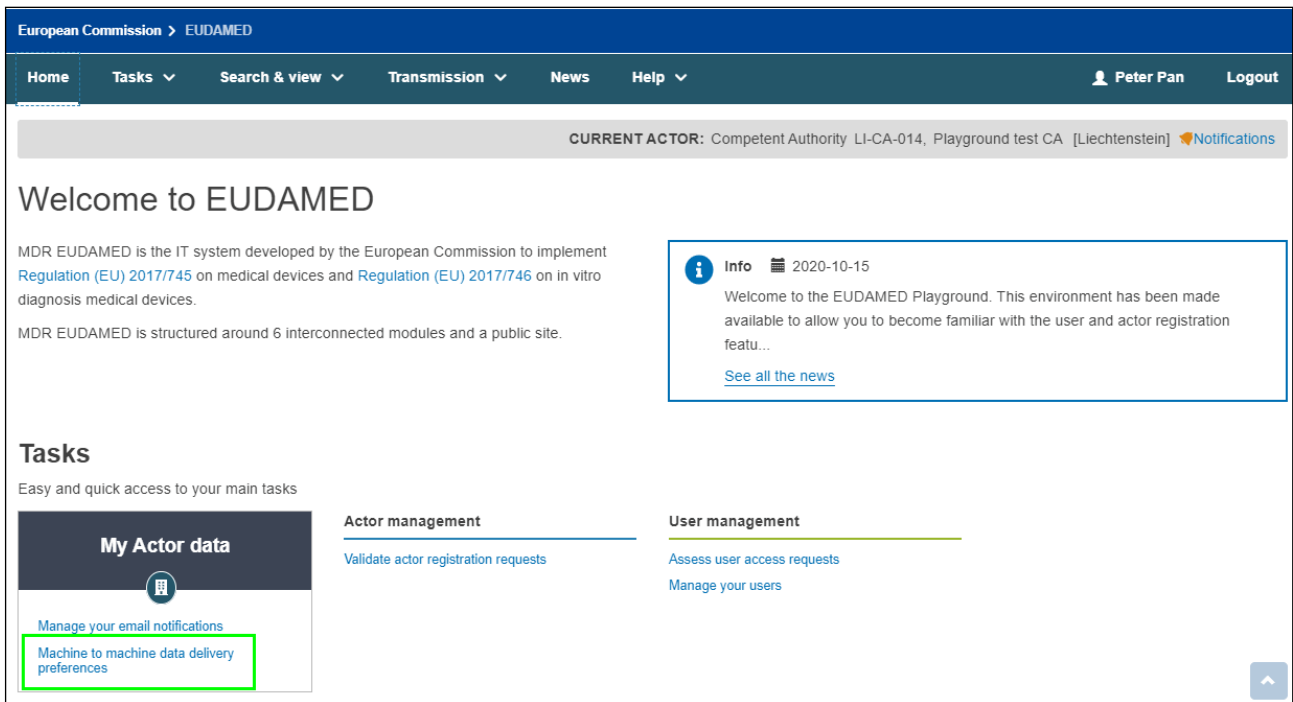


Figure 2: EUDAMED Restricted Dashboard for Competent Authority

The preferences are defaulted to “No” as a security measure:

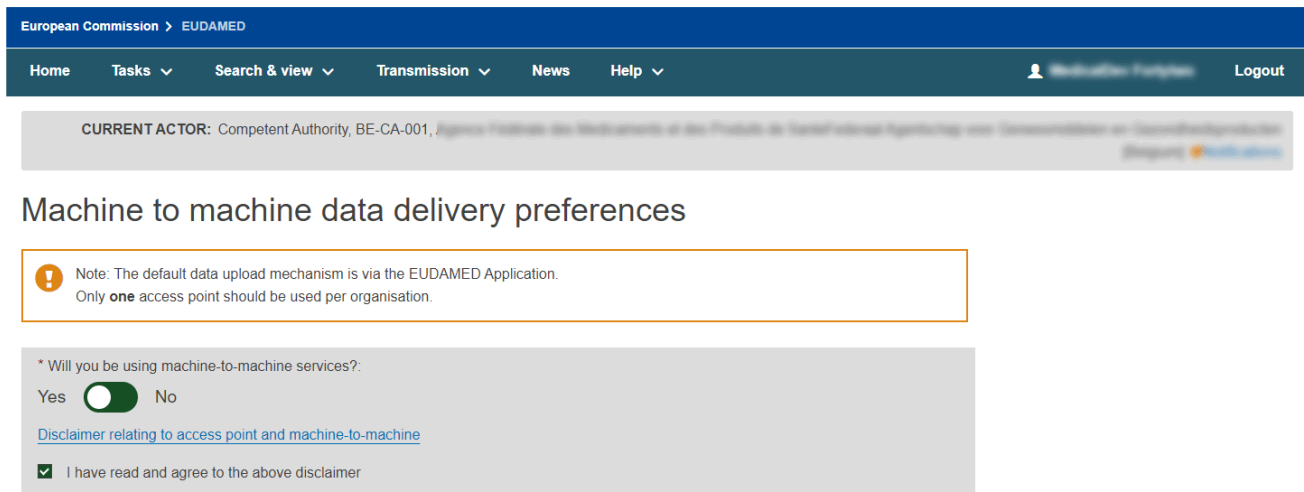


Figure 3: Machine to machine preferences

2. Select “Yes”, read and agree to the disclaimer. You will be presented with a list of services available to you. This list is specific to your actor type. Select the services you wish to activate and whether you require a new access point configuration:

Data exchange services

Please select the services you wish to use for data exchange

* **Services list**

Actor download

Device download

Device upload

How many devices do you intend to exchange data on?

Access point request information

* **Access point request**

[CEF eDelivery access point documentation](#)

Do you want to apply for a new access point configuration?

Yes No

Do you already have your own eDelivery access point?

Yes No

Is this access point already configured for EUDAMED?

Yes No

Figure 4: Machine to machine services and request information for a manufacturer

- If you require a new access point configuration, you will be asked to enter technical and legal contact details. Economic operators (i.e. non-supervisory bodies) who choose to use a third party must enter this information for the third party company when prompted. When you submit this information, you will be informed that this information will automatically be transmitted to the EUDAMED support team.

* **Your eDelivery access point**

The information entered below will be submitted to the EUDAMED support team. Please ensure you enter accurate details.

Technical Contact

* Contact name:

* Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

Legal Contact

* Contact name:

* Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

[Close](#)

Submission

Are you sure you want to submit your request?

The details entered will be submitted to the EUDAMED support team. **You do not need to do anything else after submitting your details.** The EUDAMED support team will be in contact via email to assist in configuration of your access point.

Figure 5: Submission of access point request information

(IMPORTANT: email notifications are disabled for the playground, so at this stage you should email [EUDAMED Support](#) to inform us you have submitted an access point request. Please ensure to include:

- Your SRN, Party ID and EU Login username
- The software you are using and your endpoint address
- If you will be using PKI service

Once approved, the support team will contact you regarding technical details of onboarding)

4. Once you confirm submission, your Party ID and access token will be displayed:

Machine to machine data delivery preferences

Will you be using machine-to-machine services?: Yes

Data exchange services

Party ID:	EUDAMED_000041
Services - Actor:	Actor download
Services - Udi-device:	Device download, Device upload

Access point request

Do you want to apply for a new access point configuration?:	Yes
Do you already have your own eDelivery access point?:	Yes
Is this access point already configured for EUDAMED?:	No

Technical Contact

Contact name:	ContactMF
Telephone:	+3212311231
Email:	contact@mf.com

Legal Contact

Contact name:	LegalMF
Telephone:	+3212311231
Email:	contact@mf.com

Your secure encrypted production codes

⚠ These codes must be included in your XML upload or download requests. Note: Codes differ per module.

Actor	0EFB8D1CA7077F3529BAAB83B0CD325B3A6B970BD1F6B2EFA847F96F14D97BB965F5428D7349D931458A9011C8658AFF70B11E88A0885D7C1C3D80E489DFCA0EB9D91A2E67267655EA5E591D5E81ADF6D0ACF6419AC4F5D747DCFO21DCD99776C3A47792EB3653D9D22673F04BFF5474986CF41DDCB88567FA36F912272A1EDE85C0E4E0F62A457FE143AE7EE53C655699EBA867906C15D0DBA181B9F19B8640737851130C991A718CB91CC15AE86F44A276B1E723741932D02D690C6A0270869419B9BEA76BFFC76C14C4E7AF26687207D5C6E29751F45D4B35761E73E3BDE3627A3E870B2BFC4E8CACA9E3B69679C040A4228E33AC47D0F9F94A277A6B1DB98655D9EB25DE1F57B987471E0E2853C2
UDI/Device	9ED1962BC8A7F016200E723FB16F1C9561C68724D3E3776B84F6F1C447E4AAD5C5F4259BA1A618195E0C2440E47A4B7BE0A963FFD1511B2E619EF8938C5D270ECB53DDAF98AF56B879D6F14C1A48321C041B1DD1E2497E1100AC186CE660D58B5E42AED4D4839A49E63CBA81911895E791821C494598844673A3E9B53089368F2B582F08BF379137CCE2E8E2952D6B91617C827E284CFB78C610FA15645844001156A432B296FF76C5B95B43892818B8959F69F1DFC3A4DC02DD18E4D9BD6ABC2CA3676235A8F2F5E452BA7C52AC981CF6585D9CE469CE95BBA7957BD206E7818E0BDA38F2AAA46902D442EA65E7E13B727FE92234C35A97FE2620559272A9BCC6D8716F170A24367F230AE71A02AE0E

[Edit](#)

Figure 6: M2M data delivery preferences overview, with Party ID and access tokens for Actor and Device module highlighted.

Specific notes for testing on the Playground environment.

- Your Actor ID/SRN, access tokens and Party ID will be DIFFERENT between Playground and Production.
- You can continue to use access points from the previous Playground
- Email notifications are DISABLED for the Playground
- You **must** successfully connect to the Playground before you can request a Production access point
- Once successfully connected, the onboarding process as above must be repeated for Production

1.3 How to update/disable your machine to machine settings

If you no longer need to use machine to machine communication, you can edit this page by clicking the Edit button, and:

- Answering “No” to “Will you be using machine to machine services?”, or
- Deselecting the specific services you do not require


Activation of new services:

- When a new release of EUDAMED includes new machine to machine services, they will NOT be active by default
- You will not be able to use newly added services until you activate them on this page

Regenerating your access token:

If you have reason to believe your token is no longer secure, you can regenerate the code by clicking the Edit button, selecting the module for which you want to regenerate the code, and clicking submit.

Your secure encrypted production codes

 These codes must be included in your XML upload or download requests. Note: Codes differ per module.

Please select the module for which you want regenerate the code (the new code will be displayed after clicking submit)

Actor

80DF55C97F46AAD511154662F3CF23B245BD034BD1772A71FBA13C4E6CC42A59E26A6A1AFE5A4C75F569623AB96AF9F6BDFD06B360D4269F20B66960407AA3675D31F5CF8739927D10A688591E73423D96DB36C870413AA6FDD210EA963E9A521F03451FB1B0BDDCE02D91A649D2D0230A4E208EE56BA0D10C47D87588CC8F2A7BD12AF016A54038E5C0C3FA8649726B44187884C3B0BF03384C32D7D2A4FE6C26E1CBA3907D9EFBBE7F150EFB930166C83617DFC5A67B19180DCBA6770153F30FA7092C4146754432A7AB8A54E7E6A064FC0227B235ADB0F3B408B9B88E25B8E8689F2FDD0DB2CEB0CB94650B80298A1B742DEA28915818E2A49FBC5E91295F5D747FF7C4BA6140C571C56526C71CCE

Figure 7: Machine to machine data delivery preferences edit page with regenerate selected for Actor module token.

Remember: When a token is regenerated, all new files submitted from this point onwards must include the new token for that module or they will be rejected.

1.4 Example of a SOAP sendMessage

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope" xmlns:ns="http://docs.oasis-
open.org/ebxml-msg/ebms/v3.0/ns/core/200704/" xmlns:_1="http://org.ecodex.backend/1_1/">
  <soap:Header>
    <ns:Messaging>
      <ns:UserMessage>
        <ns:PartyInfo>
          <ns:From>
            <ns:PartyId type="urn:oasis:names:tc:ebcore:partyid-type:unregistered">eudamed_mdr_acc</ns:PartyId>
            <ns:Role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/initiator</ns:Role>
          </ns:From>
          <ns:To>
            <ns:PartyId type="urn:oasis:names:tc:ebcore:partyid-
type:unregistered">eudamed_mdr_demo</ns:PartyId>
            <ns:Role>http://docs.oasis-open.org/ebxml-msg/ebms/v3.0/ns/core/200704/responder</ns:Role>
          </ns:To>
        </ns:PartyInfo>
        <ns:CollaborationInfo>
          <ns:Service type="tc1">bdx:noprocess</ns:Service>
          <ns:Action>TC1Leg1</ns:Action>
        </ns:CollaborationInfo>
        <ns:MessageProperties>
          <ns:Property name="originalSender">urn:oasis:names:tc:ebcore:partyid-type:unregistered:C1</ns:Property>
          <ns:Property name="finalRecipient">urn:oasis:names:tc:ebcore:partyid-type:unregistered:C4</ns:Property>
        </ns:MessageProperties>
        <ns:PayloadInfo>
          <ns:PartInfo href="cid:message">
            <ns:PartProperties>
              <ns:Property name="MimeType">text/xml</ns:Property>
            </ns:PartProperties>
          </ns:PartInfo>
        </ns:PayloadInfo>
      </ns:UserMessage>
    </ns:Messaging>
  </soap:Header>
  <soap:Body>
    <_1:submitRequest>
      <payload payloadId="cid:eudamedxmlAttachment" contentType="text/xml">
        <value>PD94bWwgdmVyc2lvbj0iMS4wliBlbmNvZGluZz0iVVRGLTgiPz4KPz4KPGhGxvPndvcmxkPC9oZWxsZ4=</value>
      </payload>
    </_1:submitRequest>
  </soap:Body>
</soap:Envelope>
```


2 BULK UPLOAD AND DOWNLOAD

Bulk requests may be sent via the EUDAMED interface in two ways:

- Click “Generate XML” to generate bulk files for download based on the results list on screen for
 - Validation of actor registration requests (as a CA Validator)
 - Search for actors
 - Search for UDI-Dis/Devices
 - Search for issued/refused certificates
- Upload files
 - Upload search criteria XML files
 - Bulk upload device XML files (new devices, updates, new UDI for an existing Basic UDI-DI)
 - Upload SS(C)P download criteria

2.1 Bulk download requests via the EUDAMED interface

2.1.1 Download actor registration requests as a CA validator

After you log in as a **CA Validator**, you will see the link “Validate actor registration requests” on your dashboard, together with a notification of how many pending requests await attention:

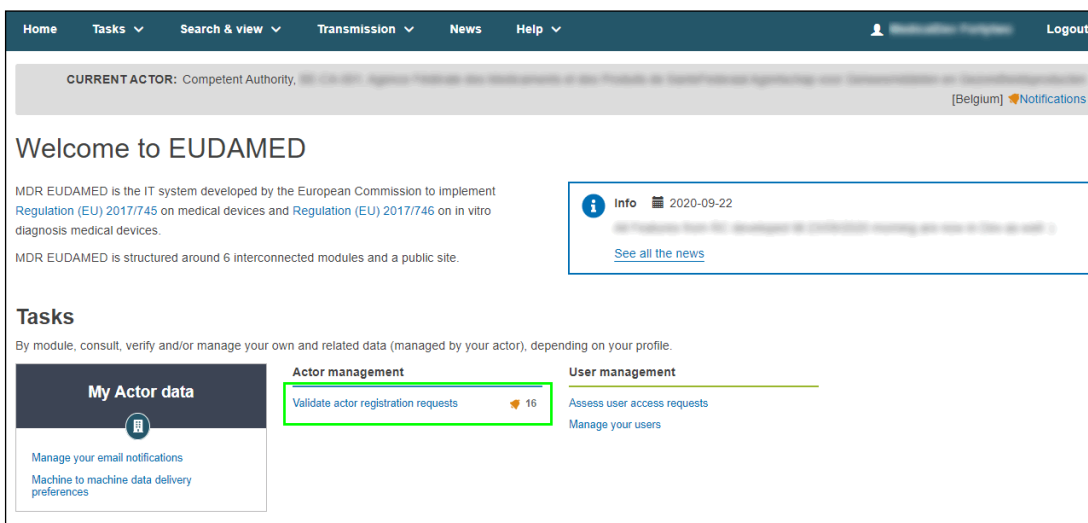


Figure 8: EUDAMED Restricted Dashboard for Competent Authority

This will bring you to the “Actor registration management” page, where you can see the list of pending requests and click “Generate XML file”:

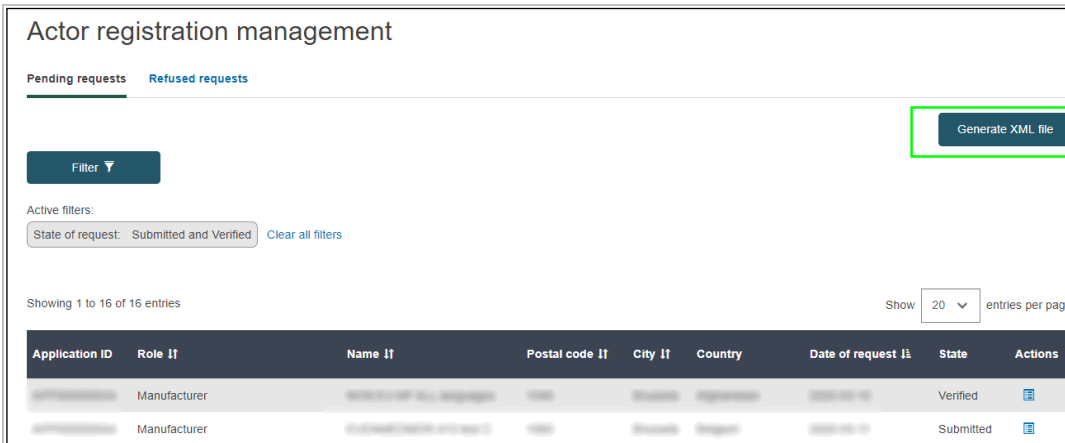


Figure 9: “Generate XML file” for pending actor registration requests

After confirming, you can click “Go to download management” to see the status of your download. When the file is processing it will receive the state “Pending”:

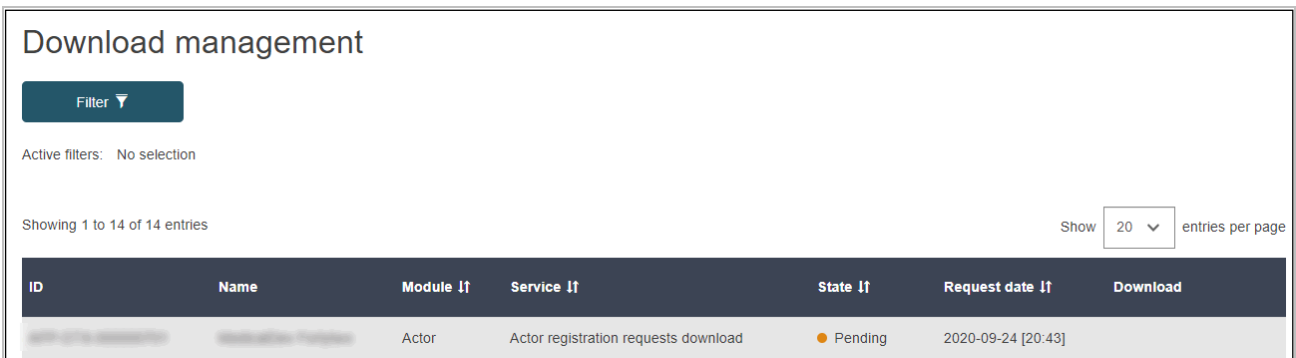


Figure 10: Download Management

Once the file is finished processing, you will see the XML file download link under the “Download” column.

2.1.2 Bulk download of actors via EUDAMED interface

In this Playground release **all actors** will be able to download registered economic operators via the EUDAMED interface. After successfully logging in, you will be able to access the actors registered in EUDAMED by using the Search and View functionalities for Actors:

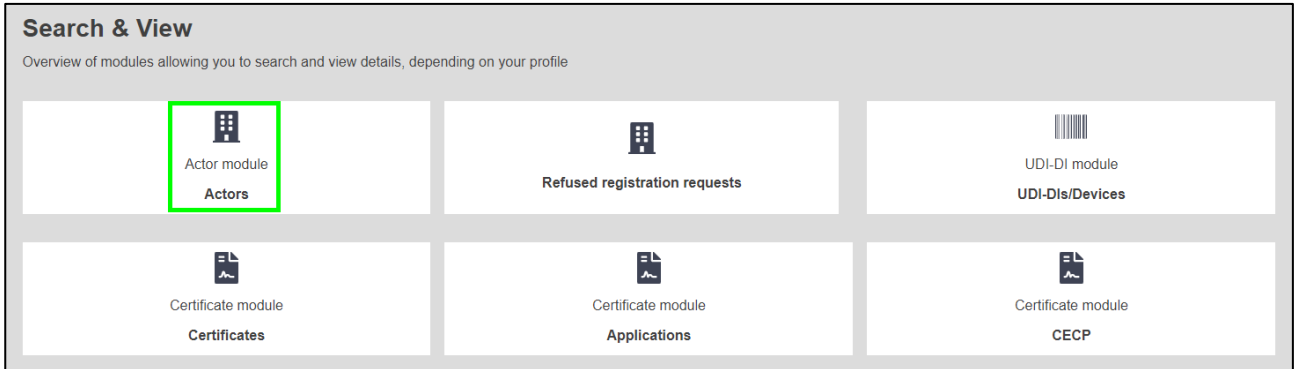


Figure 11: Search and view actors in dashboard screens

Enable the filter for bulk download of economic operators that will restrict your search criteria to those that are applicable according to the DTX service definition for actor download. You will notice that those that are not available will become shaded:

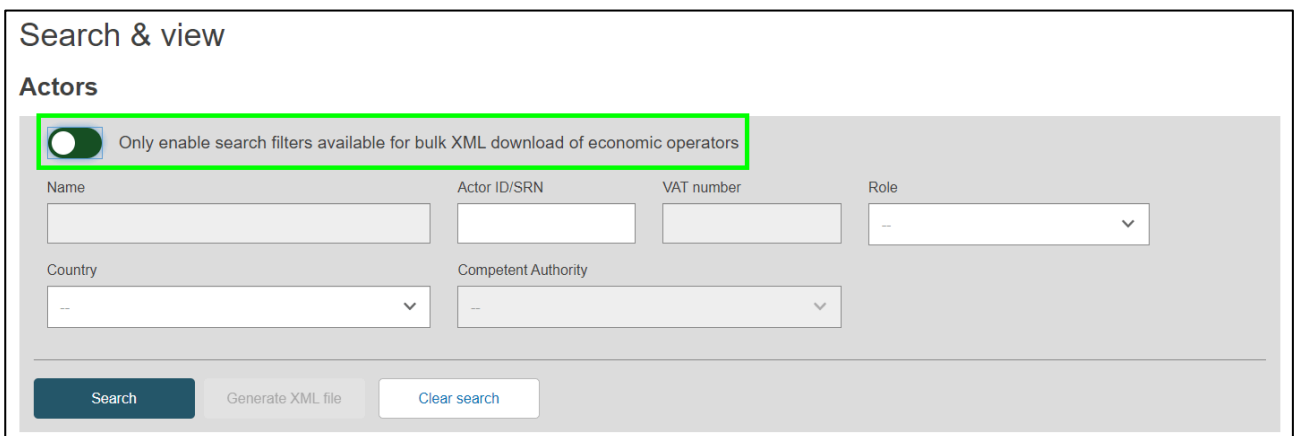


Figure 12: Filters for searching actors

After applying the desired search criteria, use the Search button in order to retrieve the list of actors. If you have provided search criteria that are not compatible with the DTX services definition, you will receive a warning prompt to amend your search.

Attention: Before using the Generate XML file button it is important to retrieve the economic operators by using the Search button, otherwise, the list returned in the XML file will not correspond with the scope of the search.

Search **Generate XML file** Clear search

Search results for actors

Active search fields:

Only enable search filters available for bulk XML download of economic operators: ✕ Actor ID/SRN: BE-MF-000000001 ✕ [Clear search](#)

Showing 1 to 1 of 1 entries Show entries per page

Actor ID/SRN <i>↑</i>	Role <i>↑</i>	Name <i>↑</i>	Country <i>↑</i>	Date of registration <i>↑</i>
BE-MF-000000001	Manufacturer	Belgium MF AV4_test [HR]	Belgium	2021-04-02

Figure 13: Generating the XML with the actor search results in the list

A confirmation message will be triggered.

After confirming, you can click “Go to download management” to see the status of your request and download the response XML files. When the file is processing it will receive the state “Pending”:

Download management

Filter

Active filters: No selection

Showing 1 to 4 of 4 entries Show entries per page

ID	Name	Module <i>↑</i>	Service <i>↑</i>	State <i>↑</i>	Request date <i>↑</i>	Download
APP-DTX-000000934	MedicalDev Fortytwo	Actor	Actor download	● Successful	2021-08-03 [15:25]	XML [7 KB] 🕒 Expires in 15 days

Figure 14: Download management list

2.1.3 Bulk download of devices via EUDAMED interface

After you log in as a user for **any actor**, you will be able to access the list of Devices registered in EUDAMED by using the Search and View functionalities for Devices:

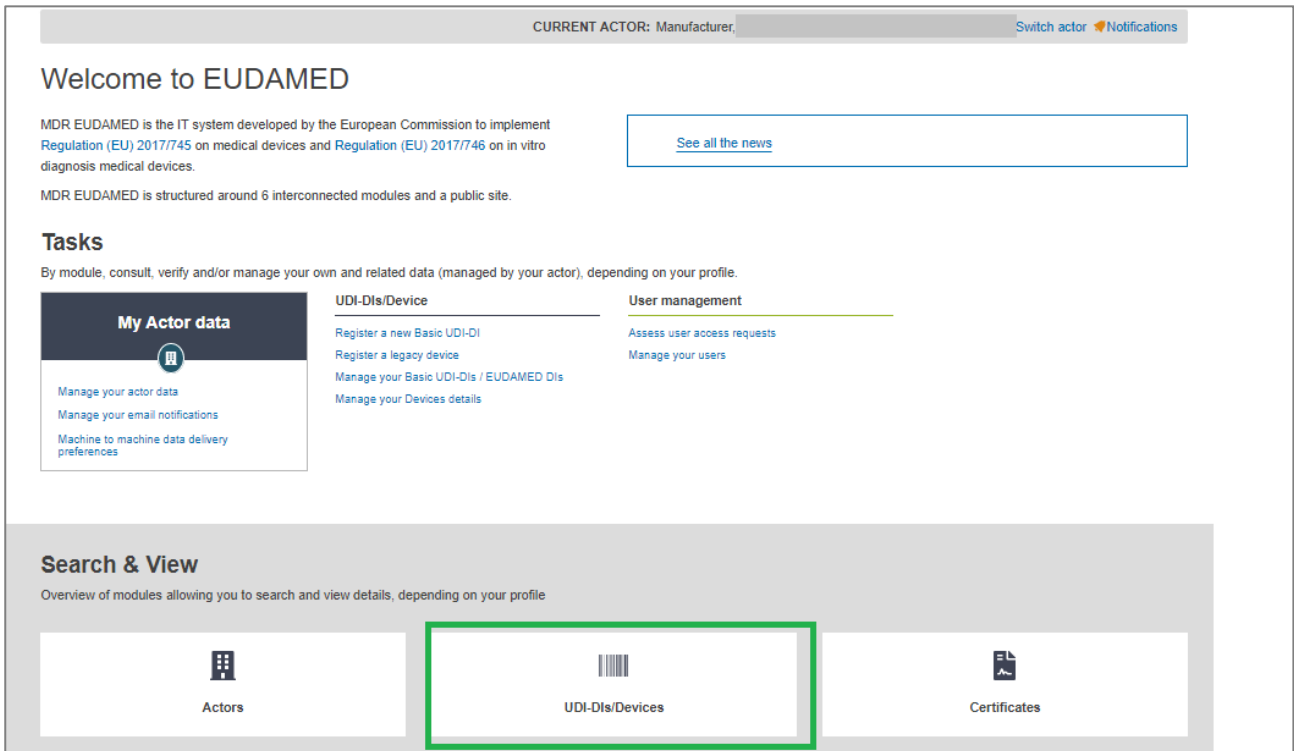


Figure 15: Search and View Devices in Dashboard screens

Apply the correct filters from the list presented in order to identify the devices that you want to download.

Attention: Use only the filters applicable in the Download Device service for Data Exchange: MFACTORCode/ PRACTORCode, ARACTORCode , BasicUDIDCode , UDIDCode, RiskClass, Country, Applicable Legislation , State.

(Please see Chapter 5 for the rules and applicability of these filters in the context of Download Devices)

The screenshot shows a web interface titled "Search for UDI-DIs". At the top, it indicates "CURRENT ACTOR: Manufacturer" and has links for "Switch actor" and "Notifications". The search form includes several input fields and dropdown menus, many of which are highlighted with green boxes. The highlighted fields are: UDI-DI code, Basic UDI-DI code, Applicable regulation (set to "MDR (REGULATION (EU) 2017/745 on medical devices)"), Risk class, Country, State (set to "Registered"), MF / PR SRN (set to "BE-MF-000000002"), and AR SRN. Other fields include Name, Trade name, Model, Nomenclature code, Reference/Catalogue number, and Scopes. At the bottom, there are buttons for "Search", "Generate XML file", and "Clear search".

Figure 16: Filters for Searching Devices

After applying the desired search criteria, use the Search button in order to retrieve the Devices.

Attention: Before using the Generate XML file button it is important to retrieve the devices by using the Search button, otherwise, the list of Devices returned in the XML file will not correspond with the scope of the search.

Search for UDI-DIs

<input type="text" value="UDI-DI code"/>	<input type="text" value="Basic UDI-DI code"/>	<input type="text" value="--"/>	<input type="text" value="Model"/>
<input type="text" value="Name"/>	<input type="text" value="Trade name"/>	<input type="text" value="Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)"/>	
<input type="text" value="--"/>	<input type="text" value="Nomenclature code"/>	<input type="text" value="Reference/Catalogue number"/>	<input type="text" value="--"/>
<input type="text" value="Registered"/>	<input type="text" value="Scopes: You can select more than one value"/>		
<input type="text" value="MF / PR SRN: BE-MF-000000002"/>	<input type="text" value="MF / PR Name"/>	<input type="text" value="AR SRN"/>	<input type="text" value="AR name"/>

Search results for devices

Active search fields: State: Registered MF / PR SRN: BE-MF-000000002 Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices) Clear search

Showing 1 to 20 of 25 entries Show 20 entries per page

UDI-DI code	Basic UDI-DI code	MF / PR SRN	Trade name	Risk class	Date	UDI-DI status
DD121	1211421211211EW	BE-MF-000000002	Trade Name	Class IIa	2021-03-23	On the EU market
1234_1235_3	2131211122348115KF	BE-MF-000000002	Generic Device Name_DEV_3	Class I	2021-03-22	On the EU market

Figure 17: Generating the XML with the Devices in the list

A confirmation message will be triggered.

After confirming, you can click “Go to download management” to see the status of your request and download the file. When the file is processing it will receive the state “Pending”:

Download management

Active filters: No selection

Showing 1 to 10 of 10 entries Show 20 entries per page

ID	Name	Module	Service	State	Request date	Download
		UDI/Device	Device download	Pending	2021-03-23 [19:16]	

Figure 18: Download management list

2.1.4 Bulk download of certificates via EUDAMED interface

For this Playground release and testing purposes, **competent authorities** and **notified bodies** will be able to download issued/refused certificates via the EUDAMED interface.

After successfully logging in, you will be able to access the list of certificates registered in EUDAMED by using the Search and View functionalities for Certificates:

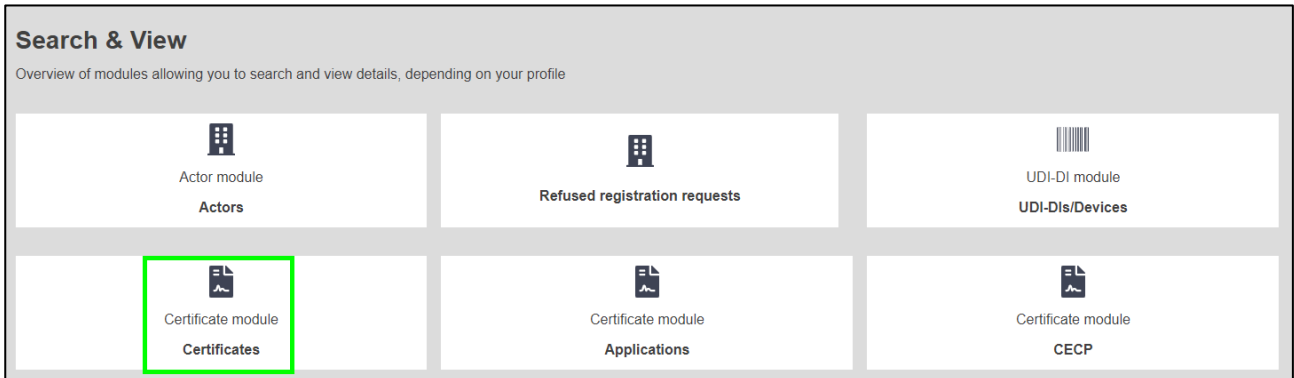


Figure 19: Search and view certificates in Dashboard screens

Enable the filter for bulk download of certificates that will restrict your search criteria to those that are applicable to the issued/refused certificate download service for Data Exchange.

The screenshot shows the "Certificates" search filter interface. At the top, there is a toggle switch labeled "Enable filters for certificates bulk download" which is turned on and highlighted with a green box. Below this, the interface includes:

- "Searching for" section with radio buttons for "Certificates" (selected) and "Refused certificates".
- "Certificate data" section with various filters:
 - NB identification: dropdown menu.
 - * Certificate Type: dropdown menu.
 - Certificate number: text input field.
 - Status: dropdown menu.
 - Economic operator Actor ID/SRN: text input field.
 - * Date of issue: "Between" and "and" date pickers (YYYY-MM-DD).
 - Date of submission: "Between" and "and" date pickers (YYYY-MM-DD).
 - Date of expiry: "Between" and "and" date pickers (YYYY-MM-DD).
- Bottom navigation: "Search" button, "Generate XML file" button, and "Clear search" button.

Figure 20: Filters for Searching Devices

After applying the desired search criteria, use the Search button in order to retrieve the certificates. If you have provided search criteria that are not compatible with the DTX services definition, you will receive a warning prompt to amend your search.

Attention: Before using the Generate XML file button it is important to retrieve the certificates by using the Search button, otherwise, the list returned in the XML file will not correspond with the scope of the search.

Search results for certificates

Active search fields:

Searching for: Certificates Enable filters for certificates bulk download: ✕ Status: Issued ✕ Between: 2021-07-01 ✕ and: 2021-07-31 ✕

Certificate Type: (MDR) EU type-examination certificate (Annex X) ✕ Clear search

Showing 1 to 2 of 2 entries Show 20 entries per page

NB number I†	MF/PR Actor ID/SRN I†	Actor ID/SRN AR I†	Certificate number I†	Certificate type I†	Date of issue I†	Date of expiry I†	Status
NB-1039	BE-MF-000000121		5317_45	(MDR) EU type-examination certificate (Annex X)	2021-07-22	2021-07-31	Issued
NB-1039	BE-MF-000000001		2222222	(MDR) EU type-examination certificate (Annex X)	2021-07-05	2022-01-07	Issued

Figure 21: Generating the XML with the certificates in the list

A confirmation message will be triggered.

After confirming, you can click “Go to download management” to see the status of your request and download the response XML and ZIP files. When the file is still processing it will receive the state “Pending”:

Download management

Filter ▾

Active filters: No selection

Showing 1 to 3 of 3 entries Show 20 entries per page

ID	Name	Module I†	Service I†	State I†	Request date I†	Download
APP-DTX-000000930	MedicalDev Fortytwo	Certificates/Notified Body	Certificate download	● Pending	2021-08-03 [15:00]	
APP-DTX-000000836	MedicalDev Fortytwo	Certificates/Notified Body	Refused Certificate download	● Successful	2021-07-26 [12:35]	ZIP [165 KB], XML [11 KB] ⌚ Expires in 7 days
APP-DTX-000000826	MedicalDev Fortytwo	Certificates/Notified Body	Refused Certificate download	● Successful	2021-07-26 [10:18]	ZIP [165 KB], XML [11 KB] ⌚ Expires in 7 days

Figure 22: Download management list

2.2 How to upload a file

The file upload screen can be found for **all users** under Transmission > Upload menu when you are logged in with the relevant profile:

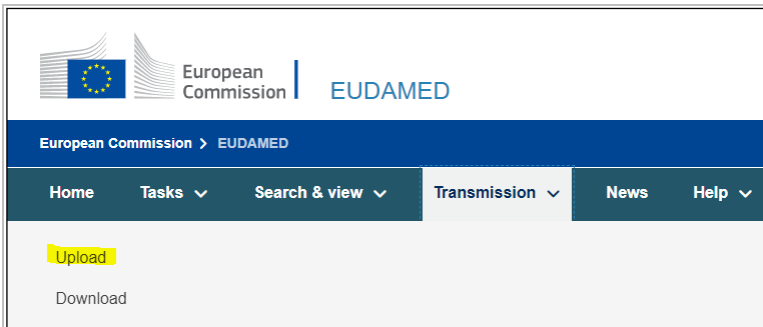


Figure 23: “Upload” menu item in top navigation menu

Click on “New upload” to see the file upload screen:

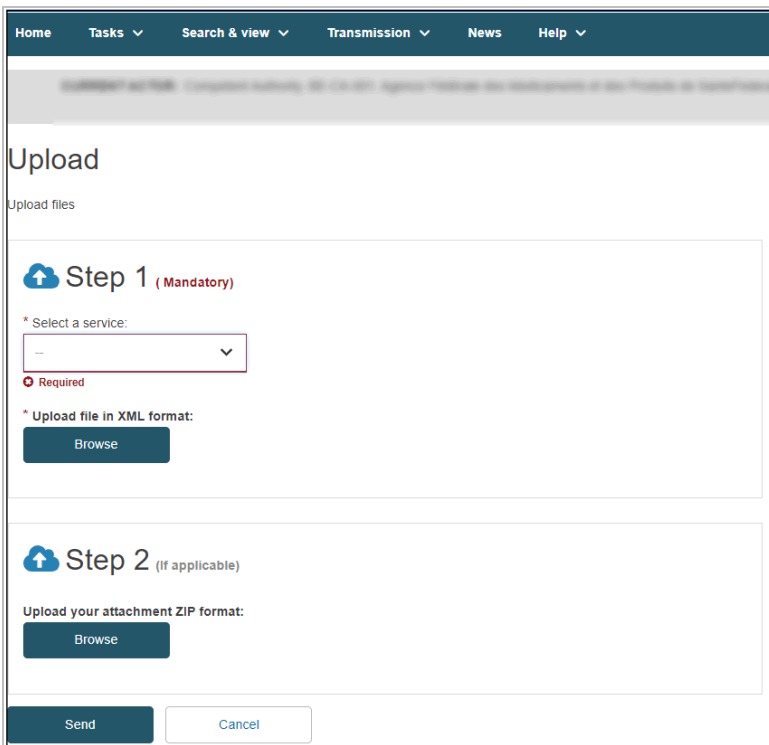


Figure 24: “Upload” page – Mandatory XML file

In this screen, you may select the desired service and attach an XML file for upload. Available services depend on which actor you are logged in as.

Once uploaded, click on “Go to upload management” to see your pending upload. When the file has completed processing, you will see the XML response download link under the “Response” column:

The screenshot shows the 'Upload management' interface. At the top right is a 'New upload' button. Below it is a 'Filter' button. The text 'Active filters: No selection' is displayed. Below that, it says 'Showing 1 to 12 of 12 entries'. On the right side, there is a 'Show' dropdown menu set to '20' and the text 'entries per page'. Below this is a table with the following columns: ID, Name, Service ID, State ID, Request date ID, Uploaded, Response date ID, and Response. The table contains one row with the following data: ID (partially obscured), Name (partially obscured), Service ID 'Actor registration assessments upload', State ID 'Pending' (with a yellow dot), Request date ID '2020-09-24 [20:49]', Uploaded 'XML', Response date ID '-', and Response '-'. There are also two small icons on the left side of the table header.

ID	Name	Service ID	State ID	Request date ID	Uploaded	Response date ID	Response
[partially obscured]	[partially obscured]	Actor registration assessments upload	● Pending	2020-09-24 [20:49]	XML	-	-

Figure 25: “Upload Management” page – Pending requests

3 XML SAMPLES DESCRIPTIONS

3.1 Actor Sample Description

The sample XML files outline the expected structure for upload, but **must** be adapted in order to match the details required for **your actor’s circumstances**. For example, a registration request assessment file must identify the correct actor and application IDs for a successful outcome.

Use case	XML file name	Description	Result
UC_BLK_ACT_001: Download registered actors	SAMPLE_DTX_ACT_REQ_V1.5_001.01.xml	Search for an individual manufacturer SRN (EU)	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.02.xml	Search for an individual manufacturer SRN (non-EU)	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.03.xml	Search for an individual importer	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.04.xml	Search for an individual authorised representative	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.05.xml	Search for an individual producer	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_001.07.xml	Request to download a registered economic operator using the wrong attribute type in the pull request	Negative
UC_BLK_ACT_002: Download actor registration requests	SAMPLE_DTX_ACT_REQ_V1.5_002.01.xml	Download a specific application ID (includes Zip attachment)	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_002.02.xml	Request containing incorrect end tag – XSD invalid	Negative
	SAMPLE_DTX_ACT_REQ_V1.5_002.03.xml	Request a specific initial submission date with a mix of EU and non-EU Producers (includes Zip attachments)	Positive
UC_BLK_ACT_003: Upload actor registration request assessments	SAMPLE_DTX_ACT_REQ_V1.5_003.01	Approve EU manufacturer	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_003.02	Unknown APPLICATION-ID Provided	Negative
	SAMPLE_DTX_ACT_REQ_V1.5_003.03	One upload containing an approved and a correct assessment	Positive
	SAMPLE_DTX_ACT_REQ_V1.5_003.04	Negative assessment with reason: Duplicate	Negative

3.2 UDI/Device Sample Description

Use case	XML file name	Description	Result
UC_BLK_UDI_001 : Download of Basic UDI-DI, UDI-DI and device data	UDI_REQ_V1.5_004.01 (MF).xml	Request Download Device (BUDI and UDI-DI) information using a combination of the following criteria: Basic UDIDI Code, UDIDI code, MF actor code, AR actor code MF and State Filtering Criteria	Positive
	UDI_REQ_V1.5_004.06 (MF, Country).xml	Request Download Device (BUDI and UDI-DI) information using a combination of the following criteria: Basic UDIDI Code, UDIDI code, MF actor code, AR actor code Criteria : Manufacturer (State is automatic Registered), Country	Positive

3.3 Certificate Sample Description

Use case	XML file name	Description	Result
UC_M2M_CRF_02 : Download issued certificate (last current version)	SAMPLE_DTX_CRF_REQ_V1.5_02.01.xml	Downloading explicitly a known certificate by its certificate number.	Positive
	SAMPLE_DTX_CRF_REQ_V1.5_02.02.xml	Downloading certificates that reference a specific manufacturer by specifying its SRN	Positive
	SAMPLE_DTX_CRF_REQ_V1.5_02.03.xml	Downloading certificates issued by other Notified Body than the Notified Body requestor.	Negative
UC_M2M_CRF_03 :	SAMPLE_DTX_CRF_REQ_V1.5_03.01.xml	Download refused certificates by its number	Positive

Use case	XML file name	Description	Result
Download refused certificate	SAMPLE_DTX_CRF_REQ_V1.5_03.02.xml	Download refused certificates by type	Positive

3.4 SS(C)P Sample Description

Use case	XML file name	Description	Result
UC_M2M_UDI_009 : Download SSCP	SAMPLE_DTX_UDI_REQ_V2.0_009.01.xml	Download SS(C)P by Basic UDI-DI	Positive
	SAMPLE_DTX_UDI_REQ_V2.0_009.02.xml	Download SS(C)P by certificate ID	Positive

4 DTX EXCEPTIONS

EUDAMED data exchange involves some layers of validation before successful delivery and response. These occur via several layers of validation:

4.1 XSD validation

The XSD schema is the first layer of validation and further information can be found within the XSD files. These ensure that the following correctly match what is expected:

- Datatype
- Field length
- Occurrence
- Enumeration match
- XML file structure

Below you will find an example of an XSD validation error:

```
<message:report>
<message:elementReport>
<message:operationErrorCode>E-I-40000</message:operationErrorCode>
<message:operationErrorDetail>[ValidationProblem { line=32, column=44, type=ERROR, message='cvc-enumeration-valid: Value 'XX' is not facet-valid with respect to enumeration '[AR, IM, MF, PR]'. It must be a value from the enumeration.' }, ValidationProblem { line=32, column=44, type=ERROR, message='cvc-type.3.1.3: The value 'XX' of element 'service:type' is not valid.' }]: please fix the message validation issues and resend it</message:operationErrorDetail>
</message:elementReport>
</message:report>
```

4.2 Error codes

SERVER_ERROR:

This is a general error and most frequent error code returned. It is also returned if there is any outbound validation error or something goes wrong while processing.

INVALID_REQUEST_OBJECTS:

This error code is returned when the request XML contains any element that could not be mapped to known objects by the EUDAMED data exchange.

SERVICE_NOT_FOUND:

This error code is returned when the service requested is not available (yet) in EUDAMED data exchange.

In addition to the above codes, sub-codes are returned which are generated dynamically and accompany further details as part of an error report (see above XML sample in section 1.5.1 for example). These codes are listed in the Annex - 1 to this document.

5 M2M ENVIRONMENTS

Name	Purpose	Test Data Purge Timing	Version Management	Notifications
Playground	External test & Demo	May be purged based on new releases	New version or current version	No

Production	Real data	Never	Current version	Yes
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6 SUPPORT

Domain	Contact	Service
EUDAMED Support	SANTE-EUDAMED-SUPPORT@ec.europa.eu	The FIRST point of contact for starting onboarding Generating/regenerating the access token XSD/XML validation and error responses Data dictionary queries Bug reporting and feature suggestions
Access point support	Multiple sources may contact user, but all replies should go through SANTE-EUDAMED-SUPPORT@ec.europa.eu	Access point connection (once approved by EUDAMED support) Public Key Infrastructure (PKI) queries Pmode configuration Advice on AS4 conformant solutions Configurations for getting the message to EUDAMED

7 SUPPORTING DOCUMENTS

Documentation	Content
DTX XSD	The XML Schema Definition for the available services and entities
DTX Samples	Bulk upload samples covering the most used scenario's per service These are general samples, not containing personalized data.
DTX Service Definition	A business level view of the available services
DTX Business Rules	All constraints related to the services
Enumerations	Value lists for multiple choice fields
Data Dictionaries	Explains the Entity structure and meta data about their attributes

ANNEXES

7.1 Annex - 1: Error sub-codes

GENERIC_INTERNAL_50000("50000"),
UNSUPPORTED_MESSAGE_TYPE_50001("50001"),
EDELIVERY_BRIDGE_READ_NULL_ID_50001("E-B-50001"),
INBOUND_VALIDATION_GENERIC_NULL_OBJECT_I_50001("I-50001"),

INBOUND_VALIDATION_DOWNLOAD_ACTOR_NULL_IMESSAGE_I_50002("I-50002"),
INBOUND_VALIDATION_ACTOR_DOWNLOAD_UNSUPPORTED_SRN_I_50003("I-50003"),
INBOUND_VALIDATION_DOWNLOAD_ACTOR_NULL_IMESSAGE_I_50004("I-50004"),
INBOUND_VALIDATION_CREATE_DEVICE_NULL_IMESSAGE_PAYLOAD_I_50005("I-50005"),
INBOUND_VALIDATION_WRONG_DOWNLOAD_ACTOR_PAYLOAD_TYPE_I_50006("I-50006"),
INBOUND_TRANSFORM_PULL_REQUEST_NULL_MESSAGE_I_50007("I-50007"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_DOWNLOAD_CRITERIA_WRONG_TYPE_MESSAGE_I_50008("I-50008"),
INBOUND_VALIDATION_DOWNLOAD_DEVICE_NULL_IMESSAGE_I_50009("I-50009"),
INBOUND_VALIDATION_DOWNLOAD_DEVICE_NULL_IMESSAGE_PAYLOAD_I_50010("I-50010"),
INBOUND_TRANSFORM_PULL_REQUEST_DEVICE_DOWNLOAD_CRITERIA_NULL_MESSAGE_I_50011("I-50011"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_DOWNLOAD_CRITERIA_WRONG_TYPE_MESSAGE_I_50012("I-50012"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_REGISTRATION_NULL_MESSAGE("I-50013"),
INBOUND_VALIDATION_INVALID_XML_PAYLOAD_I_40000("I-40000"),
INBOUND_VALIDATION_NULL_XML_PAYLOAD_I_40001("I-40001"),
INBOUND_VALIDATION_NULL_OBJECT_PAYLOAD_I_40002("I-40002"),
INBOUND_VALIDATION_SERVICE_ID_I_40003("I-40003"),
INBOUND_VALIDATION_NULL_ACTOR_DOWNLOAD_CRITERIA_PAYLOAD_I_40004("I-40004"),
INBOUND_VALIDATION_NULL_CRITERIA_PAYLOAD_I_40005("I-40005"),
INBOUND_VALIDATION_NULL_DEVICE_DOWNLOAD_CRITERIA_PAYLOAD_I_40006("I-40006"),
INBOUND_VALIDATION_NULL_INBOUND_PAYLOAD_I_40007("I-40007"),
OUTBOUND_TRANSFORM_OBJ_TO_XML_NULL_MESSAGE_O_50001("O-50001"),
OUTBOUND_TRANSFORM_OBJ_TO_XML_NULL_RESPONSE_MESSAGE_O_50002("O-50002"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_ACTOR_DOWNLOAD_NULL_MESSAGE_O_50003("O-50003"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_ACTOR_DOWNLOAD_WRONG_PAYLOAD_TYPE_O_50005("O-50005"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_DEVICE_DOWNLOAD_NULL_MESSAGE_O_50006("O-50006"),
OUTBOUND_TRANSFORM_PULL_RESPONSE_DEVICE_DOWNLOAD_WRONG_PAYLOAD_TYPE_O_50007("O-50007"),
OUTBOUND_TRANSFORM_DOWNLOAD_DEVICE_IDENTIFIER_O_50002("E-O-50002"),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50010("O-50010"),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50011("O-50011"),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50012("O-50012"),
OUTBOUND_VALIDATION_NULL_MESSAGE_O_40000("O-40000"),
OUTBOUND_VALIDATION_NULL_MESSAGEID("O-40001"),
OUTBOUND_VALIDATION_NULL_RESPONSE_O_40002("O-40002"),
OUTBOUND_VALIDATION_NULL_RESPONSE_MESSAGEID("O-40003"),
IO_VALIDATION_NULL_IMESSAGE_50000("E-IO-50000"),
IO_VALIDATION_NULL_IMESSAGE_50001("E-IO-50001"),
E_I_VALIDATION_NULL_IMESSAGE_50000("E-I-50000"),
E_I_VALIDATION_NULL_IMESSAGE_PAYLOAD_XML_50001("E-I-50001"),
E_I_VALIDATION_INVALID_XML_PAYLOAD_40000("E-I-40000"),
E_O_VALIDATION_NULL_IMESSAGE_50000("E-O-50000"),
E_O_VALIDATION_NULL_IMESSAGE_PAYLOAD_XML_50001("E-O-50001"),
E_O_VALIDATION_INVALID_XML_PAYLOAD_O_50002("E-O-50002"),
M_VALIDATION_GENERIC_M_50000("M-50000"),

INBOUND_TRANSFORM_PUSH_REQUEST_DEVICE_UPLOAD_NULL_MESSAGE("RESERVED_X_60001"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_ADD_NULL_MESSAGE("RESERVED_X_60002"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_UPDATE_NULL_MESSAGE("RESERVED_X_60003"),
INBOUND_TRANSFORM_PUSH_REQUEST_BUD_UPDATE_NULL_MESSAGE("RESERVED_X_60004"),
INBOUND_TRANSFORM_PUSH_REQUEST_MARKET_UPSERT_NULL_MESSAGE("RESERVED_X_60005"),
INBOUND_TRANSFORM_PUSH_REQUEST_DEVICE_UPLOAD_WRONG_TYPE_MESSAGE("RESERVED_X_60101"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_ADD_WRONG_TYPE_MESSAGE("RESERVED_X_60102"),
INBOUND_TRANSFORM_PUSH_REQUEST_UDI_UPDATE_WRONG_TYPE_MESSAGE("RESERVED_X_60103"),
INBOUND_TRANSFORM_PUSH_REQUEST_BUD_UPDATE_WRONG_TYPE_MESSAGE("RESERVED_X_60104"),
INBOUND_TRANSFORM_PUSH_REQUEST_MARKET_UPSERT_WRONG_TYPE_MESSAGE("RESERVED_X_601005"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UPLOAD_NULL_MESSAGE("RESERVED_X_60501"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_ADD_NULL_MESSAGE("RESERVED_X_60502"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_UPDATE_NULL_MESSAGE("RESERVED_X_60503"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_BUD_UPDATE_NULL_MESSAGE("RESERVED_X_60504"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_DEVICE_UPLOAD_WRONG_MESSAGE_TYPE("RESERVED_X_60601"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_ADD_WRONG_MESSAGE_TYPE("RESERVED_X_60602"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_UDI_UPDATE_WRONG_MESSAGE_TYPE("RESERVED_X_60603"),
OUTBOUND_TRANSFORM_ACKNOWLEDGEMENT_BUD_UPDATE_WRONG_MESSAGE_TYPE("RESERVED_X_60604"),
VALIDATION_MALFORMED_URI("RESERVED_X_61001"),
SERVICE_VALIDATION_INVALID_ENTITY_40000("SERVICE_VALIDATION_40000"),
INBOUND_TRANSFORM_PULL_REQUEST_ACTOR_REGISTRATION_PAYLOAD(("I-50014")),
OUTBOUND_TRANSFORM_DOWNLOAD_ACTOR_ACTOR_TYPE_O_50013("O-50013");